Filed Under Seal Pursuant To 31 U.S.C. § 3730(b)(2)

UNITED STATES OF AMERICA, ***ex rel.* Jess Kruchoski and Luke Tornquist,** **Relators,** **v.** **MiMedx Group, Inc.,** **Defendant.**	**CIVIL ACTION NO. 0:17-sc-00187 DSD-BRT** **AMENDED COMPLAINT** **JURY TRIAL DEMANDED** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

Relators Jess Kruchoski and Luke Tornquist, by and through their attorneys, bring this Complaint on behalf of the United States for damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq.* and allege as follows:

INTRODUCTION

1. Since at least 2013, Defendant has been defrauding the United States in the sale of human tissue grafts through the Department of Veterans Affairs Multiple Award Schedule. Instead of selling those grafts at the price offered its most favored customers, Defendant has charged the Government a higher price by lying about commercial sales in the disclosure required to get on the Multiple Award Schedule. Defendant's failure to provide truthful, complete, and accurate information about the pricing offered to its most favored commercial customers has resulted in overcharges to the federal Government totaling tens of millions of dollars.

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JURISDICTION AND VENUE

2. This Court has jurisdiction over this lawsuit pursuant to 28 U.S.C. § 1345 and 31 U.S.C. § 3732(a).

3. Defendant transacts business in this District by selling its products to customers, including the Department of Veterans Affairs, in this District. Venue in this District is proper pursuant to 28 U.S.C. 1391(c) and 31 U.S.C. 3732(a).

4. Relators are aware of no statutorily-relevant public disclosure of the allegations or transactions in this Complaint. Even if such a disclosure had occurred, relators are an "original source" of the allegations in this Complaint and meet the requirements of 31 U.S.C. § 3730(e)(4)(B). Relators acquired direct and independent knowledge of the information on which the allegations in this Complaint are based, and voluntarily and in good faith provided this information to the Government before filing this action.

PARTIES

5. The United States of America is the plaintiff on whose behalf Relators bring this action under 31 U.S.C. § 3729 *et seq.* The United States acts through its various agencies and departments, including the General Services Administration (GSA), the Department of Veterans Affairs (VA), the Small Business Administration (SBA), and other relevant government payors.

6. Relator Jess Kruchoski is a former MiMedx employee. During his employment, Kruchoski frequently performed work on behalf of MiMedx in

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Minnesota. In July 2012, he started his employment at MiMedx as an Account Executive of Government Sales for the company's Wisconsin and Minnesota territories. In October 2013, MiMedx promoted Kruchoski to Regional Sales Director of the North Central Region. He held this position until his termination on December 12, 2016.

7. Relator Luke Tornquist is a former MiMedx employee. He was Account Executive of MiMedx's Greater Minneapolis territory from October 2013 until his termination on December 12, 2016. Under Kruchoski's leadership, Tornquist became MiMedx's number one sales representative in the United States.

8. Defendant MiMedx Group, Inc. is a Florida corporation with its principal place of business in Marietta, Georgia. MiMedx is listed on the NASDAQ stock exchange and employs about 500 employees. In 2015, it reported annual revenue of $187.3 million with an operating profit of $29.4 million. In 2016, it reported annual revenue of $246.8 million.

THE VA MULTIPLE AWARD SCHEDULE PROGRAM

9. Executive agencies of the United States may procure products and services only through full and open competition, unless they meet certain exceptions. 41 U.S.C. § 253(a)(1).

10. The competitive bidding process and the negotiation of contractual terms are lengthy and costly processes. To expedite the procurement process for executive agencies and contractors wishing to sell products to executive agencies, the

General Services Administration, through the Federal Acquisition Service, has established a procedure to solicit, negotiate, award and administer Multiple Award Schedule (MAS) contracts. 41 U.S.C. § 251 *et seq.*; 40 U.S.C. § 501(b). The MAS is also known as the "Federal Supply Schedule" (FSS). The GSA has negotiated multiple schedules for different types of procurement, including, for example, schedules offering professional services, hardware, travel services, and leasing of automobiles and light trucks.[1]

11. By a delegation of authority from the GSA, the Department of Veterans Affairs (VA) solicits, negotiates, awards, and administers Multiple Award Contracts to procure medical supplies under the VA Federal Supply Schedules program. 48 C.F.R. § 8.402(a). Purchases from the VA Multiple Award Schedules are made not only by the VA, but also by many government agencies.[2]

12. The VA manages nine Multiple Award Schedules, including, for example, Drugs, Pharmaceuticals & Hematology Related Products, X-Ray Equipment & Supplies, Professional & Allied Healthcare Staffing Services, and the schedule relevant to the products at issue here, Medical Equipment & Supplies, which is labeled Schedule 65 II A.[3]

13. The process for awarding a VA MAS contract to a contractor is like that used by the GSA, except that the VA National Acquisition Center, rather than the

[1] https://www.gsa.gov/portal/category/101334
[2] http://www.fss.va.gov/
[3] https:// www.va.gov/oal/business/fss/schedules.asp

GSA, negotiates the MAS contracts with individual contractors who want to be listed on the schedules. 48 C.F.R. § 808.402.

14. Under the VA MAS program, the VA negotiates prices and contract terms with individual vendors that will apply to subsequent orders placed for all the items that are covered by the MAS contract. The list of products or services available for purchase under an MAS contract is referred to as the contract "schedule." The pre-negotiation of the terms of sale of many products and services under the MAS program saves administrative time for Government agencies ordering from the MAS and for contractors wishing to sell products to the government.

15. The MAS program also allows the Government to obtain commercial supplies and services at prices associated with volume buying. 41 U.S.C. § 259(b)(3); 48 C.F.R. § 8.402(a). Additionally, agencies placing orders under MAS contracts are considered to meet the requirements of full and open competition. 48 C.F.R. § 8.404(a).

16. Contractors benefit from the MAS program, because they do not have to compete in sealed bidding or negotiated acquisitions, and their products are more widely available to federal agencies under one central contract, thus making it easier for the contractor to secure revenue.

17. As described by the VA, its schedules "are indefinite delivery/indefinite quantity type contracts awarded to pre-approved vendors using full and open competition. Additionally the FSS program negotiates firm-fixed pricing based on a

commercial 'most favored customer' pricing concept, including an option for economic price adjustments."[4]

18. Key regulations related to federal purchasing are provided in the Federal Acquisition Regulations (FAR) at 48 C.F.R. 1-53.303. More specifically, regulations related to Federal Supply Schedules are provided at 48 C.F.R. § 8.4 and the General Services Administration Acquisition Manual (GSAM), which contains 48 C.F.R. §§ 501.1- 570.802.[5] Finally, regulations specifically relating to the VA are found at 48 C.F.R. §§ 801-873.118, called the VA Acquisition Regulation (VAAR) policies. The VAAR specifically states that its procedures "shall be used in conjunction with the Federal Acquisition Regulation," unless there is a variance in the VAAR, in which case the VAAR applies. 48 C.F.R.§ 801.

19. The VA, through its National Acquisition Center, initiates an MAS process by publishing a contract solicitation. An interested contractor then submits its proposal in response to the solicitation.

20. The contract proposal is then assigned to and evaluated by a Contract Specialist who collects any needed additional information, engages in negotiations, analyzes the pricing and overall proposal, and submits the final proposal for review and decision by the VA.

[4] http://www.fss.va.gov/

[5] Because of pending changes in parts of 48 C.F.R. at §§ 501.1- 570.802, the GSAM has proven to be the most complete source of the cited regulations, compared to other online sources. Accordingly, cites to these sections of 48 C.F.R. will be to the GSAM.

21. If an MAS is awarded, the contract is assigned an FSS contract number, and the contractor is required to publish relevant information including a price list in three forms: (1) as an Authorized FSS Paper Price List schedule that can be distributed and posted online; (2) on the NAC Contract Catalogue Search Tool Price List, accessible online ; and (3) on the GSA *Advantage!* Electronic Price List., also accessible online.

When Negotiating MAS Contracts, Offerors Are Required to Make Complete and Accurate Disclosures of Their Pricing and Discounting Policies and Practices

22. The current VA Solicitation for Schedule 65 II A (Medical Equipment & Supplies) (65 II A Solicitation)[6] states in its introductory materials that awards are based on a "best value" determination defined as an "expected outcome" that "provides the greatest overall benefit in response to the requirement." 48 C.F.R. § 2.101.

23. To achieve this goal, the MAS program is built around a vertical pricing model where pricing offered to the Government from a potential vendor is compared to the pricing that the same vendor offers to its commercial customers.

24. The 65 II A Solicitation, through Solicitation Clause 52.215-20, requires an offeror to prepare and submit an offer in accordance with Solicitation Clause 552.212-70. That clause requires the production of the offeror's commercial descriptive catalog or price list from which any discount is offered. The clause further

[6] This VA Solicitation may be found at https://www.fbo.gov/index?s=opportunity&in its =form&id=2635434a2316eba47bb361cd2d153799&tab=core&_cview=1

directs that any price list specially produced for purpose of the offer must "represent a verbatim extract" from the catalog or price list underlying the document. Solicitation Clause 552.212-70(c)(1). The offeror must also indicate, for each item offered, any concessions proposed that are not offered to commercial customers and any discounts offered under the solicitation. Solicitation Clause 552.212-70(c)(3)-(4).

25. Solicitation Clause 552.212-70(a) defines concessions and discounts as follows:

> (i) *Concession* means a benefit, enhancement or privilege (other than a discount), which either reduces the overall cost of a customer's acquisition or encourages a customer to consummate a purchase. Concessions include, but are not limited to freight allowance, extended warranty, extended price guarantees, free installation and bonus goods.
>
> (ii) Discount means a reduction to catalog prices (published or unpublished). Discounts include, but are not limited to, rebates, quantity discounts, purchase option credits, and any other terms or conditions (other than concessions) which reduce the amount of money a customer ultimately pays for goods or services ordered or received. Any net price lower than the list price is considered a "discount" by the percentage difference from the list price to the net price.

26. Solicitation Clause 52.215-20 also requires an offeror to submit additional pricing information in the "Commercial Sales Practice Format" (CSP) found at Figure 515.4-2 in the GSAM at § 515.408 or in a spreadsheet provided with the Solicitation that asks for the same information. Included in the CSP is the commercial list price charged for each product offered, as well as information about other proposed terms and conditions.

27. .The Government further states in Solicitation Clause 52.215-20 that it "expects" the offeror to provide information that is "current, accurate, and complete as of 14 calendar days prior to its submission." GSAM § 515.408 at Figure 515.4-2.

28. MAS contractors who are not manufacturers of the products, but rather dealers or resellers, must provide commercial sales information about the suppliers of the product the MAS contractor sells to the federal government. GSAM § 515.408(b) (at (5) in the Commercial Sales Practice Format).

29. Pursuant to GSAM § 538.270-1(c), contracting officers are required to use the provided "evaluation methodology for negotiating MAS offers when the commercial sales practices format is included in the solicitation (see 515.408)." That methodology includes a goal that the Government "will seek to obtain the offeror's best price (the best price given to the most favored customer)" although "there may be legitimate reasons why the best price is not achieved." GSAM § 538.270-1(c). When determining the reasonableness of a price, the contracting officer is directed to "*compare the terms and conditions of the MAS solicitation with the terms and conditions of agreements with the offeror's commercial customers.*" GSAM § 538.270-1(e) (emphasis added).

30. Regarding this negotiation objective, the GSA, in its Final Rule effective August 21, 1997, states that contracting officers are "to take full advantage of the Government's leverage in the market to obtain the best price (most favored customer) based on an evaluation of discounts, terms, and conditions and concessions offered to commercial customers for similar purchases." 62 Fed. Reg. 44518. Evident throughout

the Final Rule is the expectation that the Government would purchase commercial items through the MAS as much like commercial customers as possible.

31. In negotiating the terms of an MAS contract, government contracting officers therefore rely heavily on the accuracy and, of course, truthfulness of the information provided by the offeror regarding its commercial sales in negotiating the terms of an MAS contract.

32. MAS contracts provide that if, after the formation of the contract, the Government discovers that the prices in a contract or modification were inflated due to the contractor's failure to provide current, accurate, and complete information, or to update that information, the Government is entitled to a reduction in the price of each order issued pursuant to the MAS contract. GSAM § 552.215-72 (incorporated by reference into the Schedule 65 II A Solicitation at GSAM § 552.215-71.). The amount of the reduction is the amount by which the Government orders were inflated because of the inaccurate or undisclosed information. *Id.*

The Price Reductions Clause Requires MAS Contractors to Provide the Government with Improvements to the Commercial Pricing and Discounts Set Forth in Their Disclosures

33. The 65 II A Solicitation incorporates Solicitation Clause 552.238-75 regulations related to price reductions. This "Price Reductions Clause" (PRC) requires the offeror and contracting officer to agree on: (1) a basis-of-award customer; and (2) the Government's price or discount relationship to that customer. *See* GSAM § 552.238-75(a). "Any change in the contractor's commercial pricing or discount

arrangement applicable to the identified customer (or category of customers) which disturbs this relationship shall constitute a price reduction." *Id.*

34. Under the terms of the PRC at GSAM § 52.238-75(c)(1), a price reduction occurs if the contractor:

> (i) Revises the commercial catalog, pricelist, schedule or other document upon which the contract award was predicated to reduce prices;
>
> (ii) Grants more favorable discounts or terms and conditions than those contained in the commercial catalog, pricelist, schedule or other documents upon which the contract award was predicated; or
>
> (iii) Grants special discounts to the customer (or category of customers) that formed the basis of the award, and the change disturbs the price/discount relationship of the Government to the customer that was the basis of the award.

35. When a price reduction to the benefit of the basis-of-award commercial customer occurs, the contractor must offer the same price reduction to the Government, with the same effective date and for the same time period; this must occur within 15 days of the effective date of the price reduction. *See* GSAM § 552.238-75(f).

36. If a contractor's discount practices vary by model or product line, the discount information should be by model or product line as appropriate. GSAM § 515.408 Fig. 515.4.

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FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

MiMedx's Business

37. Human placental tissue has been used for decades to promote wound healing. The amnion and chorion layers of the amniotic membranes are rich in growth factors that support the healing process.

38. Due to logistical issues surrounding the availability of fresh amnion, risks of blood-borne pathogens, and the need for surgeons to source from their own hospitals' OB-GYN ward, the use of amnion (the innermost membrane that encloses the embryo) was never commercially viable.

39. That has changed. One of MiMedx Group, Inc.'s (MiMedx) subsidiaries developed a proprietary method that safely and effectively manipulates placental tissue to create implants for a wide variety of surgical applications. Essentially, the process involves dehydrating and sterilizing the tissue. The process gives the tissue a shelf life of up to five years at ambient room temperature. MiMedx has developed several products for acute and chronic wound care with this proprietary method.

A History of MiMedx's Relationship with the MAS Program

40. AvKARE, Inc. (AvKARE) is a Tennessee corporation with a principal place of business in Pulaski, Tennessee.

41. On April 19, 2012, MiMedx and AvKARE entered into a Product Distribution Agreement (Agreement). At the time of the Agreement, MiMedx lacked its own MAS contract. MiMedx saw an opportunity to take advantage of AvKARE's

status as a disabled-veteran-owned small business and Federal Supply Schedule contractor. MiMedx entered into the Agreement so it could sell its products to lucrative government accounts using the MAS program's streamlined procurement process.

42. Since the inception of the Agreement, AvKARE has been distributor in name only. AvKARE plays no role in the distribution or sales process. It never exercises possession or control of MiMedx's products, nor does AvKARE play a role in reselling MiMedx's products to government accounts. Rather, MiMedx sends its own sales representatives to government accounts to procure purchase orders for its own products. MiMedx sales and customer service representatives process the purchase orders, and in turn MiMedx ships its product directly to the government accounts.

43. On January 20, 2015, MiMedx obtained its own authorization to sell products under the MAS program. Nevertheless, in April 2015, MiMedx extended its distributor agreement with AvKARE, Inc. through June 30, 2016, and later again through June 30, 2017. MiMedx now purports to sell its products under both its and AvKARE's MAS contracts. It appears MiMedx continued its relationship with AvKARE to perpetuate a channel-stuffing scheme designed to artificially inflate its revenue and deceive investors.

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MiMedx Product Lines: EpiFix and AmnioFix

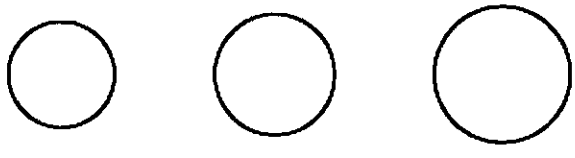
44. This action involves the EpiFix and AmnioFix line of MiMedx allografts. An allograft is a tissue graft that is transplanted from one person to another.

45. EpiFix is a dehydrated human amnion/chorion membrane tissue graft composed of a layer of epithelial cells, a basement membrane, and an avascular connective tissue matrix.

46. MiMedx's AmnioFix product line is marketed and sold for internal healing. To create its AmnioFix models, MiMedx allegedly scrapes the epithelial layer off its allografts, leaving only the basement membrane and an avascular connective tissue matrix. Whereas EpiFix allografts possess an epithelial layer, AmnioFix allografts do not.

47. MiMedx offers EpiFix in a variety of shapes and sizes. In its marketing materials, MiMedx boasts that EpiFix has size-appropriate grafts to minimize waste and reduce the overall "cost of closure."[7]

48. The EpiFix models relevant to this action are the 14-millimeter, 16-millimeter, and 18-millimeter disks:



From left to right: actual sizes of the 14-mm, 16-mm, and 18-mm EpiFix disks

[7] MiMedx Website, *Reduce Cost to Closure and Minimize Graft Wastage with EpiFix* (accessed Dec. 5, 2016) ("With multiple size appropriate grafts, EpiFix represents cost savings in the treatment of acute and chronic wounds."), *available at* http://mimedx.com/products/reducing-wastage.

49. Other than the negligible differences in size, the disks are identical in composition and clinical efficacy.

50. Physicians use EpiFix to treat chronic non-healing wounds in various types of patients. According to MiMedx's commercial marketing materials, the two largest categories of chronic wound types are diabetic foot ulcers and venous leg ulcers.

51. The median size of a diabetic foot ulcer is 1.35 square centimeters.

52. The 14-mm EpiFix disk has a surface area of 1.5 square centimeters—larger than the median surface area of a diabetic foot ulcer.

53. The median surface area of a venous leg ulcer is 2.32 square centimeters.

54. The 18-mm EpiFix disk has a surface area of 2.54 square centimeters—larger than the median surface area of a venous leg ulcer.

MiMedx Is Defrauding the Government

55. MiMedx's fraudulent pricing schemes involve materially false and misleading statements and omissions in CSP disclosures that the company provides as a condition to selling its products under the MAS program.

Fraud No. 1: The False Price Fraud

56. MiMedx has lied to the Government about claimed commercial sales of its 16-mm EpiFix disk. In CSP disclosures to the Government, MiMedx claims that it sells the disk to commercial customers at the list price of $995.00. In fact, MiMedx does not sell the 16-mm disk to its commercial customers at all. MiMedx offers its

commercial customers only smaller- and larger-sized disks at price points *lower* than $995.00.

Fraud No. 2: Fraudulent Manipulation of Product Offerings

57. As stated above, MiMedx *does not offer or sell* 16-mm disks to the commercial sector. Conversely, MiMedx *only* offers and sells the 16-mm disks to the Government under AvKARE's and MiMedx's MAS contracts. MiMedx does not offer or sell the 14-mm or 18-mm disks to the Government.

58. In Kruchoski's experience, sales of the 16-mm disks to the government were substantially higher than any other product on MiMedx's MAS schedule.

59. Both the 14-mm and 18-mm disks MiMedx offers its commercial customers are cheaper per disk and per square millimeter than the 16-mm disks MiMedx offers the government through the MAS program.

(i) MiMedx sells the 16-mm disk to the government at a price point of $895.00.

(ii) MiMedx offers its most favored commercial customers the 14-mm and 18-mm disks at $299.50 and $685.50, respectively.

(iii) The commercial list prices for the 14-mm and 18-mm disks are $375.00 and $795.00, respectively.

(iv) MiMedx offers its most favored commercial customers the 14-mm disk for $595.50 less than the 16-mm disk MiMedx offers the Government. The only difference between the two disks is that the 16-mm disk is a negligible .47 square centimeters *larger*.

(v) MiMedx offers its most favored commercial customers the 18-mm disk for $209.50 less than the 16-mm disk MiMedx offers the Government. The only difference between the two disks is that the 16-mm disk is a negligible .53 square centimeters *smaller*.

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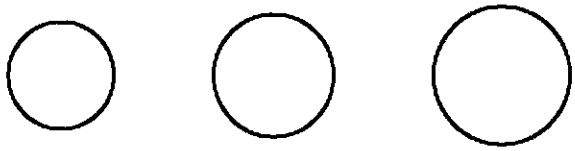


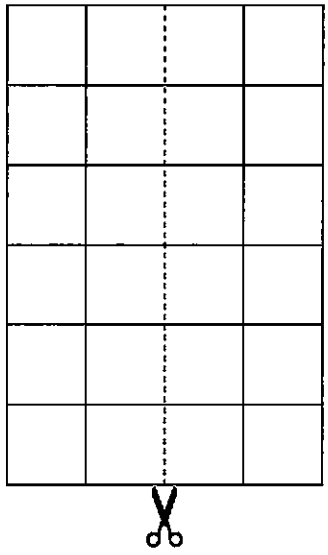
	14-mm Disk	16-mm Disk	18-mm Disk
Surface Area	1.54 cm^2	2.01 cm^2	2.54 cm^2
Most Favored Commercial Customer Price	**$299.50**	**Not Offered**	**$685.50**
MAS Price for Government	**Not Offered**	**$895.00**	**Not Offered**
Cost Per Millimeter	$21.35	$55.94	$38.05

Hence, the Government pays more per disk and per square centimeter for a 16-mm disk than the commercial sector pays for either a 14-mm or 18-mm disk, despite no difference in composition or clinical efficacy between the models.

60. MiMedx promotes AmnioFix for internal uses such as surgical tendon wraps, nerve wrap and scarring protection, enhanced tissue healing after surgery, and decreased scarring after incision.

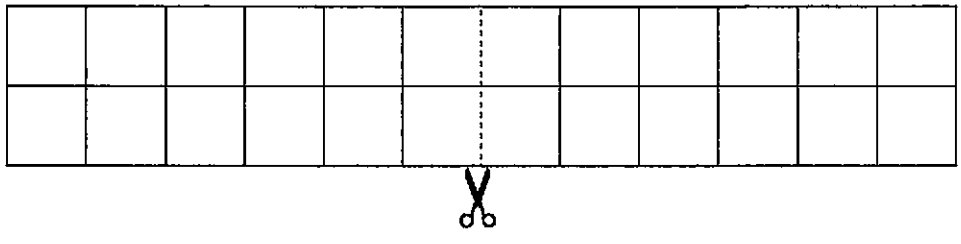
61. MiMedx has always offered a 4 cm x 6 cm AmnioFix allograft sheet (AAS-5460) to both its commercial and government customers.

62. Over time, MiMedx learned that AmnioFix sheets could protect nerves exposed after a radical prostatectomy. As part of this therapeutic use, treating physicians bisect the 4 cm x 6 cm AmnioFix sheet into two 2 cm x 6 cm sheets before application, like so:



63. Seeing a sales opportunity, MiMedx promoted the use of the 4 cm x 6 cm AmnioFix sheet for treating nerves after a radical prostatectomy. However, commercial customers generally did not see enough benefit to pay the 4 cm x 6 cm allograft's list price, $2,695.00, or its most-favored-customer price, $1,800.00.

64. In response to commercial health care providers' unwillingness to pay for the 4 cm x 6 cm allograft for post-radical prostatectomy nerve treatment, in 2015 MiMedx developed a 2 cm x 12 cm AmnioFix sheet (APS-5212) for the same therapeutic use but at a lower price point. MiMedx designed the 2 cm x 12 cm AmnioFix sheet so that treating physicians could— as with the 4 cm x 6 cm allograft— bisect it into two 2 cm x 6 cm sheets before application, like so:



65. MiMedx does not offer the 2 cm x 12 cm AmnioFix sheet to the Government through the MiMedx or AvKARE MAS accounts. Rather, MiMedx developed the 2 cm x 12 cm AmnioFix sheet for the sole purpose of giving commercial clients a steep discount while evading its contractual and regulatory obligation to provide a reciprocal discount to the Government.

66. Hence, MiMedx continues to charge the Government $1,800.50 for 4 cm x 6 cm AmnioFix sheet while offering most-favored commercial customers the 2 cm x 12 cm allograft for only $994.50. In sum, MiMedx charges the Government about *twice as much* as commercial customers.

AmnioFix Sheet Size	Surface Area	Most Favored Commercial Customer Price	MAS Price
4 cm x 6 cm	24 cm^2	$1,800.50	$1,800.50
2 x12 cm	24 cm^2	$994.50	**Not Offered**

Fraud No. 3: Providing CSP Information That Is Untruthful, Inaccurate, and Incomplete

67. On December 8, 2016, MiMedx Executive Vice President Deborah L. Dean amended Blanket Purchase Agreement[8] (BPA) No. VA119-16-A-0465 under MiMedx's MAS contract, effective December 13, 2016.

[8] A blanket purchase agreement is a simplified acquisition method that government agencies use to fill anticipated repetitive needs for supplies or services. BPAs are like "charge accounts" set up with trusted suppliers.

68. The purpose of the amendment was to add three additional MiMedx products under the BPA: EpiFix 7 cm x 7 cm grafts, EpiFix Micronized 160 mg grafts, and EpiCord 3 cm x 5 cm grafts.

69. As part of the amendment process, the Department of Veterans Affairs asked MiMedx to add the new pricing data for the three additional products to an existing spreadsheet detailing pricing and product information. The spreadsheet contained pricing and product information that MiMedx had previously provided to the Department of Veterans Affairs.

70. The spreadsheet shows that MiMedx represented, and continues to represent, to the Government that the commercial price of EpiFix's 16-mm disk is $995.00— a materially false statement.

71. The spreadsheet contains no pricing information on the 14-mm or 18-mm EpiFix disks. The spreadsheet also contains no pricing information on the 2 cm x 12 cm AmnioFix sheets. Nor are Relators aware that MiMedx ever provided information about these products to the Government or to AvKARE in the initial negotiations or in the process of negotiating amendments for any MAS contract.

72. It is reasonable to conclude that MiMedx has omitted and continues to omit from its MAS solicitation and subsequent modifications material pricing discounts or concessions it gives its most favored commercial customers for the 2 cm x 12 cm AmnioFix model as well as the 14-mm and 18-mm EpiFix models.

73. It is also reasonable to conclude that MiMedx has withheld and continues to withhold from the Government complete information about its commercial sales of the same products because that information would reveal that it was charging the Government significantly more for the 16-mm EpiFix disk and the 4 cm x 6 cm AmnioFix sheet than it was charging for essentially the same commercial products. That is, MiMedx failed to provide the necessary information for the Government to make an accurate determination whether the prices offered to the Government were fair and reasonable.

74. Finally, it is reasonable to conclude that AvKARE similarly did not provide complete information about MiMedx's products to the Government when adding them to its MAS contract. It is unknown whether AvKARE is complicit in MiMedx's fraud or whether AvKARE relied on MiMedx to provide it with truthful, accurate and complete pricing information, which AvKARE, in turn, provided to the Government.

75. The false and misleading statements and omissions integral to Frauds 1, 2 and 3, were material to the Government's initial and ongoing determinations that the prices for the 16-mm EpiFix disk and the 4 cm x 6 cm AmnioFix sheet were fair and reasonable. Because the commercial sales information was required by the Government as a basis for comparing prices and making its own determination that the prices were fair and reasonable, the Government clearly viewed that information as

"having a natural tendency to influence, or be capable of influencing the payment or receipt of money." 31 U.S.C. 3729(b)(4).

76. Because of MiMedx's materially false and misleading statements and omissions, the United States overpaid by millions of dollars for MiMedx products sold under MiMedx's and AvKARE's MAS contracts.

MiMedx's Fraud Is Systemic and Violates the False Claims Act

77. MiMedx's fraudulent concealment of more favorable pricing information was intentional, systemic, and top-down. Price lists for commercial and Government buyers were centrally created and provided to MiMedx's Account Executives (*i.e.*, its direct sales representatives).

78. Executive Vice President Deborah Dean's awareness of MiMedx's CSP disclosures is evident in her participation in the December 8, 2016 amendment of a BPA Agreement.

79. Within his first month at MiMedx, Kruchoski asked Vice President of Sales Operations Mark Diaz why MiMedx did not offer the Government the cheaper 14-mm disk through the MAS contracts. Diaz responded that MiMedx would not offer the 14-mm disk to the Government because the Government would pay for the more expensive 16-mm disk.

80. Diaz also specifically and emphatically instructed Kruchoski to never share a commercial price list with prosthetics directors and doctors at VA facilities. Kruchoski understood from Diaz's comment that MiMedx believed the Government

would not pay for the 16-mm disk at its current MAS price if the Government were made aware that commercial customers were receiving the 14-mm and 18-mm disks at a fraction of the MAS list price. This demonstrates that the pricing schemes discussed above were intentional, knowing, and emanated from the top levels of the company.

81. Only individuals in high-level management positions at MiMedx could authorize such statements and omissions in the company's CSP disclosures. Furthermore, individuals in high-level management positions within MiMedx, such as Executive Vice President Deborah Dean, have periodically reviewed CSP disclosures as part of maintaining MiMedx's right to sell under the MAS program. After these reviews, high-level managers have deliberately and repeatedly failed to correct misrepresentations and omissions in CSP disclosures MiMedx has provided the Government.

82. Accordingly, MiMedx has knowingly, intentionally and successfully schemed to defraud the Government of millions of dollars under the MAS program by making or causing to be made false claims for payment by the Government and false records or statements material to a false or fraudulent claim in violation of the FCA, 31 U.S.C. § 3729(A)(1)(A),(B).

The Government Is Being Harmed by Defendant's Conduct

83. The Government has purchased thousands of 16-mm EpiFix disks and many 4 cm x 6 cm AmnioFix sheets at prices higher than it would have paid if it had known of MiMedx's various types of fraudulent behavior with respect to those

products. For example, on August 29, 2016, the Government executed a purchase order for one 16-mm EpiFix disk for $895.01, when commercial health care providers could have purchased a larger 18-mm disk for a significantly lower price. The Government has executed thousands of similar purchase orders for 16-mm EpiFix disks over the past several years.

84. Relator Kruchoski managed several Account Executives including Relator Tornquist, who sold about 650 16-mm Epifix disks (GS-5160) through October 2016 to VA facilities in Grand Island, Nebraska,; Minneapolis and St. Cloud, Minnesota; Houston, Texas; Iowa City, Iowa; Iron Mountain, Michigan; Milwaukee, Madison, and Green Bay, Wisconsin; and Fargo, North Dakota. The 16-mm disks, again, were sold at a price higher than a commercial health care provider would have had to pay for the larger 18-mm disk.

85. Based on informed estimations, since 2013, MiMedx has sold somewhere between 33,520 to 44,700 16-mm EpiFix disks to the Government under the AvKARE and MiMedx MAS contracts at a price point of $895.00 per disk. Hence, the United States directly paid MiMedx approximately $30,000,400.00 to $40,006,500.00 for EpiFix disks based on materially false and misleading statements or omissions.

86. In each of these transactions MiMedx submitted invoices containing or incorporating the price for 16-mm EpiFix disks under the MAS contracts.

87. Each of those invoices was fraudulent because the VA schedule prices MiMedx listed or caused AvKARE to list failed to disclose that: (1) MiMedx does not offer the 16-mm disk to its commercial customers at all; (2) the commercial sales price of a 16-mm disk is not $995.00; and (3) MiMedx offers its most favored commercial customers the negligibly smaller 14-mm disk and a negligibly larger 18-mm disk at lower price points than it offers the Government the 16-mm disk.

88. Based on informed estimations, since 2015, MiMedx has sold about fifty 4 cm x 6 cm AmnioFix sheets to the Government under the AvKARE and MiMedx MAS contracts at a price point of $1,800.00 per sheet. Hence, the United States directly paid MiMedx approximately $90,000 for 4 cm x 6 cm AmnioFix sheets based on materially false and misleading statements or omissions.

89. In each of these transactions MiMedx submitted invoices containing or incorporating the price for 4 cm x 6 cm AmnioFix allograft under the MAS contracts.

90. Each of those invoices was fraudulent because the VA schedule prices MiMedx listed or caused AvKARE to list failed to disclose that: (1) MiMedx offers its most favored commercial customers a 2 cm x 12 cm AmnioFix allograft at a price point of $994.50; and (2) physicians can bisect the 2cm x 12 cm AmnioFix allograft to create two 2 cm x 6 cm AmnioFix allografts.

91. In some instances, a government contracting official may have negotiated a discount or concession below the published VA schedule discounts MiMedx offered. However, any such negotiated discounts or concessions were

affected by a fraudulent starting point. The government contracting official seeking a discount or concession below the VA schedule discounts started by presuming that MiMedx's stated commercial list prices, discounts, and concessions reflected the best prices it offered to commercial customers. It is more likely than not that any government contracting official who negotiated prices below the VA schedule discounts on any purchase would have negotiated a proportionally higher discount if MiMedx had truthfully reported its commercial sales practices information.

COUNT I
VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

92. Relators reallege each and every paragraph of this Complaint.

93. By virtue of the acts alleged above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

94. By virtue of the acts alleged above, Defendant knowingly made, used or caused to be made or used, false records or statements material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B).

95. Defendant made claims for money directly to officers, employees or agents of the United States, 31 U.S.C. § 3729(b)(2)(A)(i), as well as to a contractor, grantee, or other recipient of money to be spent or used on the Government's behalf and to advance a Government program or interest. 31 U.S.C. § 3729(b)(2)(A)(ii).

96. The United States, unaware of the falsity or fraudulent nature of the claims presented or caused to be presented by Defendant, paid and continues to pay

amounts that otherwise would not have been paid but for Defendant's fraudulent billing.

97. Because of the Defendant's acts, and by reason of these payments given, the United States sustained damages and continues to be damaged in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act, plus the maximum civil penalty available for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

PRAYER FOR RELIEF

WHEREFORE, Relators acting on behalf of and in the name of the United States, demand and pray that judgment be entered in favor of the United States against Defendant on each count of the Complaint as follows:

A. Enter judgment for the United States Government and the Relators and against Defendant;

B. Order Defendant to cease and desist from violating the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*

C. Award the United States Government three times the amount of the actual damages sustained by the Government because of Defendant's violations of the False Claims Act as alleged in this Complaint;

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D. Assess civil penalties at the current highest rate against the Defendant for each and every false claim submitted by the Defendant to the United States Government in connection with the fraudulent conduct alleged in this Complaint;

E. Award the Relators the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d).

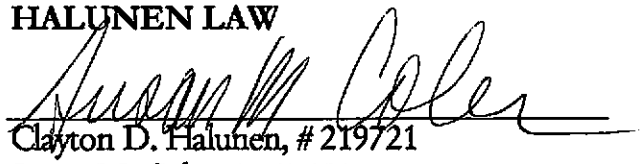
F. Award prejudgment interest; and

G. Award the Relators statutory attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d).

RELATORS DEMAND A TRIAL BY JURY ON ALL COUNTS WHERE JURY IS AVAILABLE.

Dated: January 27, 2017

HALUNEN LAW



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